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DEC 17 1979

A. H.

December 13, 1979

MEMORANDUM TO: Committee of Counsel

Enclosed is the reply brief filed by Action on Smoking and Health in the United States Court of Appeals for the District of Columbia Circuit in ASH's appeal from the district court ruling upholding FDA's determination that cigarettes are not drugs. ASH's initial brief was sent to you by memorandum dated September 14, 1979, and the Government's brief by memorandum dated November 20, 1979. ASH's motion for a postponement of the proceedings, which we sent you by memorandum dated November 14, 1979, is still pending for action by the court.

ASH's reply brief, which is fairly turgid, has two interesting aspects. First, ASH appears to have shifted its position on the requirement for showing that cigarettes are intended to be used as drugs. Previously, ASH seemed to be arguing for an interpretation of the statutory intended-use provision that could be satisfied by showing either consumers' intent or the vendor's intent. In its reply brief, however, (in the middle paragraph of page 4) ASH clearly adopts FDA's position that the vendor's intent is determinative and argues that the evidence ASH presented with respect to consumers' intent is evidence of cigarette vendors' intent.

Also, in footnote 5 on page 8, ASH seems to indicate a willingness to withdraw its appeal if FDA stipulates that the evidence presented in ASH's petition was material but insufficient on the record then before the agency. While it is impossible to know ASH's motivation for this approach, one possibility is that ASH fears the effects of an adverse decision in this case and would prefer to concentrate on its petition to have cigarette filters declared to be medical devices or perhaps to start anew on its contention that cigarettes are drugs.

Stanley L. Temko

Enclosure

cc (w/encl.):

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Source: https://www.industrydocuments.ucsf.edu/docs/ljpv0003